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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 51

2008

REGULATIONS RELATING TO THE REGISTRATION OF PHARMACISTS;
QUALIFICATIONS REGISTERED AS SPECIALITIES AND ADDITIONAL
QUALIFICATIONS; REGISTRATION AS PHARMACIST INTERN;
MAINTAINING OF REGISTERS AND THE RESTORATION OF A NAME TO
THE REGISTER: PHARMACY ACT, 2004

The Minister of Health and Social Services under section 66 of the Pharmacy Act, 2004 (Act No. 9 of 2004), read with section 27 and 31 of that Act, and on the recommendation of the Pharmacy Council of Namibia has -

- (a) made the regulations set out in the Schedule; and
- (b) repealed the regulations made under Government Notice No. R1471 of 1 August 1975.

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PART I

PRELIMINARY

Definitions

1. In these regulations, unless the context indicates otherwise, a word or expression defined in the Act bears that meaning, and -

"additional qualification" means an additional qualification referred to in section 31(1)(a) of the Act and prescribed by regulation 15;

"certified" means certified as a true copy by a commissioner of oaths appointed under section 5 or designated under section 6 of the Justices of the Peace and Commissioners of Oaths Act, 1963 (Act No.16 of 1963);

"Council" includes the Interim Pharmacy Council of Namibia, established under section 70 of the Act;

"specialist pharmacist" means a person against whose name a speciality in pharmacy is registered, and "specialist" has a corresponding meaning; and

"the Act" means the Pharmacy Act, 2004 (Act No. 9 of 2004).

PART II

REGISTRATION OF PHARMACISTS

Application for registration as a pharmacist

2. (1) An application by a person who wishes to apply for registration as a pharmacist in terms of section 21 of the Act must be accompanied, in addition to the documents, particulars and payment of fees referred to in subsection (2) of that section, by a certified photocopy of -

(a) his or her identity document or passport; and

(b) where the qualification upon which the applicant relies for registration as a pharmacist is a qualification referred to in section 23(1)(a) of the Act, the certificate of registration to practice as a pharmacist, in the country where the applicant obtained such qualification, issued by the relevant registration authority of that country.

(2) Where an applicant referred to in subregulation (1)(b) is not registered with such registration authority he or she must submit to the registrar, together with his or her application for registration, a certified copy -

(a) of such certificate issued by such registration authority, attesting to the fact that the qualification or qualifications of which the applicant is the holder entitles him or her to register as a pharmacist in that country; or

(b) if he or she had been so registered previously, of a certificate issued by such registration authority specifying the reason why the applicant is not so registered any longer.

(3) The Council may require the applicant to furnish proof, in such manner as the Council may determine, of the applicant's proficiency in the English language.

Additional examinations

3. (1) An additional examination referred to in section 23(1)(b)(ii) of the Act, in respect of a person referred to in that section, must consist of written or oral or practical examinations, or of written and oral and practical examinations, in such disciplines as the Council may determine for purposes of determining whether that person possesses the knowledge, skill and competence required to be possessed by a holder of a qualification prescribed under section 18(1) of the Act and which entitles such holder to registration as a pharmacist under section 21 of the Act.

(2) The Council may appoint, at its discretion and subject to such conditions as it may determine, suitable persons to conduct the examinations referred to in subregulation (1).

Additional education, tuition and training

4. (1) The Council must determine, when registering a person conditionally under section 23(2)(a) of the Act, the additional education, tuition or training, as the case may be, required to be undertaken by the person so conditionally registered in order for him or her qualify for registration as a pharmacist.

(2) The particulars of the additional education, tuition or training, as the case may be, determined by the Council under subregulation (1) must be endorsed by the Council upon the certificate of conditional registration issued by the Council in the name of that person under section 23(2)(b) of the Act.

PART III

PHARMACY INTERNS

Completion of internship prior to registration as pharmacist

5. (1) A person who holds a minimum qualification, prescribed under section 18(1) of the Act, for registration as a pharmacist must complete, after obtaining that qualification and before he or she is entitled to registration under the Act as a pharmacist, subject to the provisions of subregulations (3) and (7) of this regulation internship as a pharmacist intern in the manner prescribed by, and for the period referred to in, section 19 of the Act and these regulations.

(2) An application for registration as a pharmacist intern must be made and be submitted to the registrar in such form as the Council may determine.

(3) An application referred to in subregulation (2) must be accompanied by -

(a) a certificate or a certified copy thereof as proof that the applicant holds a prescribed qualification referred to in subregulation (1);

(b) a certificate of good standing, if the applicant had been registered previously in a country other than Namibia as a pharmacist intern, or is still so registered, from the registration authority with which the applicant had been so registered or is still so registered, which certificate must have been issued not more than 120 days before the date of the submission of the application for registration to the registrar in accordance with subregulation (2);

(c) a certified copy of the identity document or of the passport of the applicant;

(d) such additional documents and information as the Council may determine;

(e) a certified copy of the contract of training approved by the Council in writing under section 19(1)(c) of the Act; and

(f) proof of the payment of the application fees, determined by the Council, relating to the registration of a pharmacist intern.

(4) If an application is submitted to the registrar in accordance with this regulation, the registrar must submit such application to the Council for its consideration and decision.

(5) The Council, after having considered the application for registration and the accompanying documentation and proof of payment of the fees referred to in subregulation (3) -

(a) may grant the application if the Council is satisfied that the applicant -

(i) meets the requirements relating to the registration of a pharmacist intern;

(ii) has complied with subregulation (3); and

(iii) is proficient in the English language.

(b) must refuse the application if the Council is satisfied that the applicant -

(i) does not meet the requirements relating to the registration of a pharmacist intern; or

(ii) has not complied with subregulation (3); or

(iii) is not proficient in the English language.

(6) The Council must -

(a) inform the applicant in writing of the decision of the Council under subregulation (5);

(b) issue the applicant with a certificate of registration as a pharmacist intern, if the application as a pharmacist intern is granted, in such form as the Council may determine, and enter the name of the

applicant into the relevant register;

(c) inform the applicant in writing, if the application as a pharmacist intern is refused, as soon as practicable of the reasons for such refusal.

(7) Notwithstanding subregulation (1), the Council may exempt, on such conditions as it may determine, a person from the requirements of registration and training as a pharmacist intern in accordance with these regulations or may reduce the prescribed period of training as a pharmacist intern, by such period of time as the Council may determine, if an applicant under subregulation (2) submits together with such application documentary proof to the satisfaction of the Council that he or she has -

(a) completed, in another country and in accordance with the laws of that country pertaining to pharmacists or to pharmacist interns, training substantially equivalent to the applicable training prescribed by regulation 6, with a person or at a training facility; or

(b) practiced in another country, in accordance with the laws of that country, as a pharmacist for such period of time and under such circumstances as may afford him or her experience and training substantially equivalent to the applicable training prescribed by regulation 6.

Contract of training

6. (1) A contract of training referred to in section 19(1)(c) of the Act, entered into by and between a tutor pharmacist and a pharmacist intern, must -

(a) be in such form and contain such particulars as the Council may determine; and

(b) provide for training, in the disciplines and other requirements set out in Annexure I, which is in the opinion of the Council adequate and satisfactory for purposes of such internship.

(2) If at any time during the period of internship of a pharmacist intern referred to in this regulation, the Council considers any training approved for such purpose to be inadequate or unsatisfactory for any reason, the Council may withdraw the approval thereof by means of a written notice to both the tutor pharmacist and the pharmacist intern, after having afforded both the tutor pharmacist and the pharmacist intern the opportunity to be heard.

(3) Unless the Council determines otherwise, any period of internship completed by a pharmacist intern under a contract of training in respect of which the Council withdraws its approval in accordance with subregulation (2) is, for purposes of section 19(1)(c) of the Act, null and void.

(4) The period of pharmacist internship determined in section 19(1) of the Act must be completed within a period of two years after the date of the first registration of the relevant person as a pharmacist intern.

(5) If a pharmacist intern fails to comply with subregulation (4), his or her registration as a pharmacist intern must be regarded as cancelled, subject to subregulation (6), as from the date upon which the period of two years is exceeded.

(6) The Council may extend, on good cause shown, the two year period prescribed by subregulation (4).

(7) Before a person may commence with his or her pharmacist internship at a registered training pharmacy, he or she must -

(a) enter into a written agreement of internship with the tutor pharmacist of the training pharmacy at which he or she is to complete the internship; and

(b) register with the Council as a pharmacist intern in accordance with the Act and these regulations.

(8) Unless the Council determines otherwise, on good cause shown, any

period of internship completed by a pharmacist intern under a contract of training cancelled or terminated before the completion of the internship is, for purposes of section 19(1)(c), null and void.

(9) A pharmacist intern is subject, during his or her term of internship, to all the regulations and rules relating to professional conduct applicable to pharmacists.

(10) The Council must furnish a pharmacist intern, before the commencement of his or her internship, with a copy of the regulations and rules relating to professional conduct referred to in subregulation (9).

Cancellation or cessation of internship, or change of name

7. (1) A pharmacist intern must -

(a) notify, as soon as he or she assumes duty as a pharmacist intern with a tutor pharmacist, the Council in writing of that fact and furnish to the Council the name and business address, including the telephone number, of the tutor pharmacist with whom he or she has so assumed duty;

(b) notify, if he or she intends to terminate his or her internship with the tutor pharmacist referred to in paragraph (a), the Council in writing of such intended termination;

(c) notify, if he or she intends to cease his or her internship with the tutor pharmacist referred to in paragraph (a) and to assume internship with another tutor pharmacist, the Council in writing of such intended cessation of internship not less than 30 days before the intended date of commencement of internship at such other tutor pharmacist and submit to the Council -

(i) proof of cessation of the existing contract of training;

(ii) a certified copy of the contract of training entered

into by and between the tutor pharmacist with whom the internship is to be completed and the pharmacist intern, which agreement must be approved by the Council; and

(iii) proof of the payment of the fees, determined by the Council, relating to such cessation of the internship.

(2) If the name or surname of a pharmacist intern is changed for any reason, such pharmacist intern must -

(a) give written notice to the Council of such change, within a period of 30 days after the occurrence thereof;

(b) submit to the Council certified documentary proof of such change; and

(c) provide the Council, in writing, with such other particulars relating to such change of name or surname as the Council may require.

Completion of internship

8. (1) Upon completion of the internship undertaken by a pharmacist intern referred to in these regulations, he or she must submit proof to the Council, by way of a certificate or certificates, to the satisfaction of the Council, by the tutor pharmacist or tutor pharmacists, as the case may be, with whom he or she completed the internship, that he or she has duly undertaken and completed the internship concerned.

(2) The Council must not register a pharmacist intern as a pharmacist unless such pharmacist intern has submitted to the Council the necessary proof referred to in subregulation (1).

Evaluation to be conducted by the Council

9. (1) A person who has completed his or her internship in accordance with section 19 of the Act and with these regulations must be evaluated by the Council in accordance with section 22(3) of the Act.

(2) Notwithstanding subregulation (1), the evaluation to be conducted by the Council in accordance with this regulation may be conducted in part, at the discretion of the Council and in such manner as the Council may determine, by means of continual evaluation during the period of internship of the person concerned.

(3) The fees, determined by the Council under section 28 of the Act, relating to an evaluation referred to in this regulation must be paid to the Council before the commencement of the evaluation.

PART IV

REGISTRATION OF SPECIALITIES

AND ADDITIONAL QUALIFICATIONS

Registration of specialities

10. (1) The qualifications set out in Annexure II are the specialities prescribed under section 31(1)(b) of the Act which may be registered, subject to compliance with the requirements of these regulations, against the name of a person registered as a pharmacist under the Act.

(2) The standard of the tuition and training provided by an educational institution relating to a speciality prescribed by subregulation (1) must be adequate and satisfactory, in the opinion of the Council.

Application for the registration of a speciality and submitting of particulars

11. (1) A pharmacist who wishes to have a prescribed speciality registered against his or her name in the register must apply to the registrar in accordance with section 31(2) of the Act for such registration, and must comply with the other provisions of that section.

(2) The applicant referred to in subregulation (1) must furnish to the Council, when applying for the registration of a speciality, proof that -

(a) a period of not less than six years has lapsed from the date upon which he or she obtained the qualification entitling him or her to registration as a pharmacist;

(b) he or she obtained the qualification relating to the speciality concerned in the form of a post-graduate degree or an equivalent qualification, acceptable to the Council;

(c) he or she has practiced his or her profession as a pharmacist for a period of not less than three years; and

(d) he or she has obtained, subject to subregulation (3), not less than four years experience, relating to the qualification referred to in paragraph (a) and to the satisfaction of the Council, at a laboratory, training hospital or educational institution, under the direct supervision of a promoter, approved by the Council.

(3) The experience, referred to in paragraph (d) of subregulation (2)

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(a) gained in Namibia must be recognised by the Council only if the applicant was registered as a pharmacist to practice in Namibia during the entire period of gaining such experience;

(b) must be gained under the direct

supervision of a specialist medical practitioner registered under the Medical and Dental Act, 2004 (Act No. 10 of 2004) or a specialist pharmacist registered under section 31 of the Act, who acted as the promoter; and

(c) must include -

(i) extensive clinical experience as the incumbent of a clinical appointment approved by the Council;

(ii) practical work in a laboratory, at a university or at a training hospital, approved by the Council for such purpose,

relating to the speciality concerned and to the satisfaction of the Council.

(4) For the purpose of this regulation, "training hospital" means a hospital established or registered, or a health facility licensed, under the Hospitals and Health Facilities Act, 1994 (Act No. 36 of 1994).

Limitation on the practicing of a speciality

12. A pharmacist registered as a specialist pharmacist -

(a) must limit, subject to paragraph (b), the conducting of his or her practice to the registered speciality;

(b) may conduct, in addition to the conducting of the practice referred to in paragraph (a) and with the written approval of the Council, other pharmacy business.

Limitation on the registration and practicing of specialities

13. (1) The Council may not register more than one

speciality against the name of a pharmacist.

(2) A pharmacist may not practice more than one speciality at any point in time.

Examinations, fees and treatment of patients

14. (1) A pharmacist registered as a specialist pharmacist may charge fees, subject to subregulation (2), for conducting examinations and procedures relating to his or her patients, which examinations or procedures pertain to another pharmacy speciality, but only if such examinations or procedures are recognised, in the opinion of the Council, as generally accepted practice in the speciality for which such pharmacist is registered.

(2) The fees chargeable for examinations or procedures conducted in accordance with subregulation (1) may not be higher than the fees chargeable for such corresponding examinations and procedures conducted by medical practitioners or pharmacists practicing such other speciality.

(3) The examinations and procedures referred to in subregulations (1) and (2) must be conducted only for, or for the benefit of, the bona fide patients of the specialist pharmacist.

(4) A specialist pharmacist may treat any person who consults him or her directly, without a reference by any pharmacist or medical practitioner.

(5) A specialist pharmacist who is consulted by a patient, or who treats a patient, must take all reasonable steps to ensure the cooperation of the medical practitioner or pharmacist who normally treats that patient.

Registration of additional qualifications

15. (1) The qualifications set out in Annexure III to these regulations are the additional qualifications referred to in

section 31(1)(a) of the Act, awarded by an educational institution or other examining authority referred to in section 18(1) of the Act, which additional qualifications may be registered by the Council in respect of a person registered as a pharmacist.

(2) A qualification prescribed by subregulation (1) as an additional qualification -

(a) if such qualification is a bachelor degree, must have included in its curriculum, as one of its major subjects, not less than one of the subjects included in the minimum requirements of study for registration as a pharmacist prescribed under section 18(1) of the Act;

(b) if such qualification is a post-graduate degree, the dissertation or thesis relating thereto must be based on a subject referred to in paragraph (a);

(c) if such qualification is a Bachelor Degree in Pharmacy, the registration in Namibia of the holder of such qualification as a pharmacist must not have been based on such qualification;

(d) if such qualification is a qualifications prescribed under item (c), (e), (f) or (g) of Annexure III, must be related, to the satisfaction of the Council, to any of the prescribed requirements for practicing as a pharmacist.

Requirements for the registration of an additional qualification

16. (1) A pharmacist who wishes to have an additional qualification entered into the register against his or her name must submit to the registrar an application in accordance with subsections (2) and (3) of section 31 of the Act.

(2) An application referred to in subregulation (1) must be accompanied, in addition to the documents and particulars specified in subsection (3) of section 31 of the Act, by documentary proof that the applicant obtained a qualification relating to the additional qualification referred to in subregulation (1) in the form of a degree or of a diploma from an educational institution or from any other examining authority, and

which qualification is of a standard acceptable to the Council.

PART V

REGISTERS AND RESTORATION OF NAME TO REGISTER

Register of pharmacists

17. The register of pharmacists established and kept in accordance with subsection (2) of section 25 of the Act, must contain, in addition to the particulars specified by subsection (3) of that section, particulars of -

(a) the specialities and additional qualifications registered against the name of the pharmacist concerned in accordance with section 31(4) of the Act; and

(b) any change in any of the particulars recorded in the register.

Register of pharmacy interns

18. The register of pharmacy interns established and kept in accordance with subsection (2)(c) of section 25 of the Act must contain, in addition to the particulars specified by subsection (3) of that section, particulars of -

(a) the registered training pharmacy where the pharmacy intern is completing his or her internship;

(b) the name of the tutor pharmacist responsible for supervising the training of the pharmacist intern;

(c) the date upon which such internship commenced and is to be completed; and

(d) any change in any of the particulars recorded in the register.

Restoration of name to register

19. A person whose name has been removed from a register in accordance with section 26 of the Act and who wishes to have his or her name restored to such register must apply, in the form and manner determined by the Council, to the Council for such restoration and such application must, in addition to the documentation referred to in section 27(2) of the Act, be accompanied by -

(a) the original or certified copy of the registration certificate issued under section 22(4)(b) of the Act or, if for any reason such registration certificate cannot be submitted, proof to the satisfaction of the Council that the applicant was so registered; and

(b) a certified photo copy of the identity document or of the passport of the applicant.

PART VI

GENERAL

Language of forms and documents

20. (1) Any form or document required to be submitted to the Council or to the registrar in terms of these regulations must be, subject to subregulation (2), in the English language.

(2) Any form or document referred to in subregulation (1) that is not in the English language must be accompanied by a sworn translation thereof into the English language, acceptable to the Council.

ANNEXURE I

Criteria pertaining to the one year period pharmacy internship training programme

(regulation 6(13))

A pharmacist intern must complete the following training during his or her period of internship as the Council may direct in writing before the commencement of, or at any time during, the internship:

- (a) The preparing or compounding of medicine for the supplying thereof as medicine;

- (b) the compounding or supply of any medicine on the prescription of a medical practitioner, dentist or veterinarian, and the ensuring of the optimal use of such medicine;

- (c) the manufacturing, or the supervising of the manufacturing of, medicines;

- (d) the furnishing of advice to any person relating to medicine supplied to a patient;

- (e) the providing of pharmaceutical care to patients, including education and information on health care and medicine;

- (f) the correct manner of providing of storage for, and the distribution of, pharmaceuticals and medicines;

- (g) the conducting of research relating to, and the development of, pharmaceutical sciences and clinical pharmacology;

- (h) the understanding of the condition or conditions of a patient being treated and the appropriate treatment of such condition or conditions, including the maintenance, monitoring and assessment of patient

drug profiles;

(i) the applying of knowledge of over-the-counter products and supplying thereof to patients; and

(j) in general, the scope of practice of a pharmacist and the managing and conducting of a pharmacy practice, including the managing of the personnel and the administration of the finances of a pharmacy practice, and working as a member of a health care team.

Qualifications registered as specialities

(regulation 10(1))

Speciality

Designation

Clinical Pharmacokinetics

Clinical Pharmacokineticist

Radio-Pharmacy

Radio-Pharmacist

ANNEXURE III

Additional qualifications

(regulation 15(1))

The following qualifications may be registered as additional qualifications:

- (a) A post-graduate degree in pharmacy;
- (b) a Bachelor of Science Degree, an Honours Bachelor of Science Degree, a Masters of Science Degree or a Doctor of Philosophy (Phd.D. or D. Phil.) of Science Degree;
- (c) a Postgraduate Degree in Business Administration;
- (d) a Master of Science Degree in Pharmacy;

- (e) a Diploma in Clinical Chemistry;

 - (f) a Diploma in Biochemical Analysis; or

 - (g) a Postgraduate Specialisation Certificate.
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